PRD2008-10

Proposed Registration Decision

Sulfuryl Fluoride

(publié aussi en français)

10 June 2008

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

ISBN: 978-0-662-48957-3 (978-0-662-48958-0)
Catalogue number: H113-9/2008-10E (H113-9/2008-10E-PDF)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2008

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Overview

Proposed Registration Decision for Sulfuryl Fluoride

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Sulfuryl Fluoride Gas Fumigant and ProFume Gas Fumigant containing the technical grade active ingredient sulfuryl fluoride to control stored product pests in empty cereal grain mills, associated empty storage facilities and food processing plants.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Sulfuryl Fluoride Gas Fumigant and ProFume Gas Fumigant.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use of or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive human populations (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

---

1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on Sulfuryl Fluoride Gas Fumigant, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision document[4] on Sulfuryl Fluoride Gas Fumigant, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation in this consultation document.

What Is Sulfuryl Fluoride?

Sulfuryl fluoride is a fumigant gas that enters the insect's body either by inhalation during a life stage of active breathing (i.e. larvae, nymph or adult) or by diffusion into the egg. Sulfuryl fluoride is considered a non-specific target poison. It prevents the insect from producing the energy required to survive.

Health Considerations

Can Approved Uses of Sulfuryl Fluoride Affect Human Health?

Sulfuryl fluoride is unlikely to affect your health when used according to label directions.

Exposure to sulfuryl fluoride may occur when the product is handled and applied. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when sulfuryl fluoride products are used according to label directions.

The technical grade active ingredient sulfuryl fluoride and the end-use product ProFume Gas Fumigant are considered to be highly acutely toxic by the oral and inhalation routes. Consequently, the statement "Danger Poison" is required on each label. The compressed liquid form of sulfuryl fluoride causes cryogenic burns; therefore, the statement "Liquid is corrosive to eyes and skin" is also required on each label.

---

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*

Sulfuryl fluoride did not cause cancer in animals, was not genotoxic and did not have any impact on reproduction. The first signs of toxicity in animals exposed through inhalation to sulfuryl fluoride for short periods of time included directly observable signs (e.g. convulsions) indicative of an effect on the nervous system. Health effects in animals exposed daily to sulfuryl fluoride by the inhalation route over longer periods of time included effects on the respiratory system, brain, kidney and teeth. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

When sulfuryl fluoride was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus was not more sensitive to sulfuryl fluoride than the adult animal. However, the potential impact on the nervous system of the young was not assessed in the toxicological studies conducted with sulfuryl fluoride, which has been demonstrated to target the nervous system of the adult animal. Consequently, extra protective measures were applied in the risk assessment to further reduce the allowable level of human exposure to sulfuryl fluoride.

Occupational risks are not of concern when ProFume Gas Fumigant is used according to the proposed label directions, which include protective measures.

The label will specify that fumigation workers must wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves. It will also indicate that during fumigation and aeration, workers must wear adequate positive pressure, self-contained breathing apparatus (SCBA) with a full face mask. The label will also specify that no one may enter the treated structure without adequate respiratory protection until the concentration of sulfuryl fluoride inside the structure is at or below 1 part per million (ppm). Taking into consideration these label requirements, risk to workers handling ProFume Gas Fumigant is not of concern.

Bystander Risks From the Use of Sulfuryl Fluoride

Bystander risks are not of concern when sulfuryl fluoride is used according to the proposed label directions, which include protective measures.

A fumigation management plan is required for each fumigation event to ensure that concentrations of sulfuryl fluoride in the air around the mill do not exceed 1 ppm.

Environmental Considerations

What Happens When Sulfuryl Fluoride Is Introduced Into the Environment?

Sulfuryl fluoride is a volatile fumigant. Once released to the atmosphere, sulfuryl fluoride is expected to persist for long periods of time (approximately two decades) and is expected to be transported throughout the atmosphere (Regulatory Note REG2006-15, *Sulfuryl Fluoride*). There is limited data on the breakdown products of sulfuryl fluoride. Based on modelling conducted by the applicant, sulfuryl fluoride is expected to be a greenhouse gas.

Value Considerations

What Is the Value of ProFume Gas Fumigant?

ProFume Gas Fumigant (99.8% sulfuryl fluoride) is registered for use in empty cereal grain mills, associated empty storage facilities and empty food processing facilities to control stored product pests such as Indian meal moth, confused flour beetle, saw-toothed grain beetle, warehouse beetle and granary weevil. Stored product insects cause direct physical damage and contaminate food destined for animal and human consumption.

Sulfuryl fluoride is considered to be an alternative to methyl bromide, which has been phased out under the Montreal Protocol on Substances that Deplete the Ozone Layer.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed for inclusion on the label of ProFume Gas Fumigant to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Fumigation workers must wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves. In addition, during fumigation and aeration, workers must wear adequate positive pressure SCBA with a full face mask. The label will also specify that no one may enter the treated structure without adequate respiratory protection until the concentration of sulfuryl fluoride inside the treated structure is at or below 1 ppm. To protect bystanders around the treated structure, a fumigation management plan is required for each fumigation event to ensure that concentrations of sulfuryl fluoride in the air around the treated structure do not exceed 1 ppm.

Next Steps

Before making a final registration decision on sulfuryl fluoride, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision document, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

At the time the PMRA makes its registration decision, it will publish a Registration Decision document on sulfuryl fluoride (based on the Science Evaluation in this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Sulfuryl Fluoride

1.0 The Active Ingredient, Its Properties and Uses

A detailed assessment of the chemical properties of sulfuryl fluoride and the end-use product ProFume Gas Fumigant are presented in Regulatory Note REG2006-15, *Sulfuryl Fluoride*.

2.0 Methods of Analysis

A detailed assessment of the methods of analysis sulfuryl fluoride and the end-use product ProFume Gas Fumigant are presented in REG2006-15.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed assessment of the toxicology of Sulfuryl Fluoride Gas Fumigant and ProFume Gas Fumigant are presented in REG2006-15. No toxicology data were required as a condition of registration in 2006; therefore, no amendments or additions to the previous toxicology review were necessary.

3.2 Determination of Acceptable Daily Intake

No food uses were proposed for the Canadian registration of Sulfuryl Fluoride Gas Fumigant and Profume Gas Fumigant in these applications. As such, a food residue assessment was not required.

3.3 Determination of Acute Reference Dose

No food uses were proposed for the Canadian registration of Sulfuryl Fluoride Gas Fumigant and Profume Gas Fumigant in these applications. As such, a food residue assessment was not required.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Toxicological endpoints are presented in REG2006-15.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Handler Exposure and Risk

In the initial review for ProFume Gas Fumigant (REG2006-15), risk estimates for fumigation workers wearing protective SCBA were above the target margin of exposure (MOE). The risk estimates for workers re-entering treated structures with a concentration of 1 ppm inside the treated structure were also above the target MOE of 100 and therefore not of concern.

3.4.3 Residential Exposure and Risk

There are no domestic class products; therefore, a residential handler assessment was not required.

3.4.4 Bystander Exposure and Risk Assessment

Due to concern for bystanders in the vicinity of structures being treated with ProFume Gas Fumigant, the submission of ambient air monitoring data, from measurements performed around cereal mills/food processing plants treated with ProFume Gas Fumigant representative of Canadian climatic conditions, was required.

In the supporting data for the initial submission (REG2006-15), sulfuryl fluoride concentrations as high as 20.5 ppm were measured during the fumigation phase, and sulfuryl fluoride concentrations during the aeration phase measured a maximum of 9.8 ppm.

The ambient air concentrations of sulfuryl fluoride measured in and around a mill in Hanover, Ontario are within the range of air concentrations measured in the studies conducted in the United States, on which the original bystander risk assessment was based. This was the case, even though the Hanover mill is more than twice the size of the mills treated in the American studies. As such, the ambient air concentration around the mill does not appear to be related to the size of the mill being fumigated, and treatment of the larger Canadian cereal grain mills are not expected to result in sulfuryl fluoride concentrations higher than those observed in the studies monitored.

3.5 Food Residue Exposure Assessment

No food uses were proposed for the Canadian registration of Sulfuryl Fluoride Gas Fumigant and Profume Gas Fumigant in these applications. As such, a food residue assessment was not required.

4.0 Impact on the Environment

A detailed environmental risk assessment of Sulfuryl Fluoride Gas Fumigant and ProFume Gas Fumigant are presented in REG2006-15. No environmental data were required as a condition of registration in 2006; therefore, no amendments or additions to the previous environmental review were necessary.

5.0 Value

ProFume Gas Fumigant (99.8% sulfuryl fluoride) is effective in controlling stored product pests such as Indian meal moth, confused flour beetle, saw-toothed grain beetle, warehouse beetle and granary weevil in empty cereal grain mills, associated empty storage facilities and empty food processing facilities. For further information, refer to REG2006-15.

6.0 Toxic Substances Management Policy Considerations

For a summary of the Toxic Substance Management Policy considerations, please refer to REG2006-15.

7.0 Summary

7.1 Human Health and Safety

Fumigation workers and bystanders are not expected to be exposed to levels of sulfuryl fluoride that will result in unacceptable risk when ProFume Gas Fumigant is used according to label directions.

7.2 Environmental Risk

For a summary of the environmental risk assessment, please refer to REG2006-15.

7.3 Value

Sufficient efficacy data were submitted under the initial submission to support the proposed use claims for the control of stored product pests such as Indian meal moth, confused flour beetle, saw-toothed grain beetle, warehouse beetle and granary weevil in empty cereal grain mills, empty food processing plants and empty storage facilities.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of the technical grade active ingredient Sulfuryl Fluoride Gas Fumigant and the end-use product ProFume Gas Fumigant to control stored product pests in empty cereal grain mills, associated empty storage facilities and food processing plants. An evaluation of current scientific data from the applicant has resulted in the determination that, under the proposed conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 Impact on Human and Animal Health

PMRA 1365796 2007, Determination of Atmospheric Concentrations of Sulfuryl Fluoride During and Following Fumigation of a Mill Using Profume - Canada 2006, 060071, DACO: 5.14, 5.6, 8.6